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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/01/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,563

Applicant(s)

LEVY ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 11.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. The Office has reconsidered the prior restriction requirement, and hereby vacates the requirement in favor of the restriction set forth below. Any inconvenience this action causes the Applicant is regretted.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, and 17-18, drawn to methods of identifying NIMR activity modulators by determining the ability of a test compound to modulate NIMR polypeptide activity, classified in class 436, subclass 501.
 - II. Claims 11-16, drawn to methods of identifying NIMR expression modulators by determining the ability of a test compound to modulate expression of an NIMR polypeptide, classified in class 436, subclass 501.
 - III. Claims 19, 25, 26, 33-38 drawn to methods of decreasing the virulence of, or treating an infection by, a microbe, or of reducing marA mediated transcription of an NIMR gene, comprising exposing the microbe to an environmental challenge and a modulator of NIMR activity, classified in class 424, subclass 139.1.
 - IV. Claim 20 drawn to methods of reducing marA mediated transcription of an NIMR gene, comprising exposing the microbe to an environmental challenge and a modulator of NIMR activity, classified in class 424, subclass 139.1.

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- V. Claims 21-29, drawn to methods of identifying NIMR activity modulators by determining the ability of a test compound to bind to an isolated NIMR polynucleotide, classified in class 436, subclass 501.
- VI. Claim 30, drawn to a vaccine comprising at least one NIMR nucleic acid molecule, classified in class 536, subclass 23.1.
- VII. Claim 30, drawn to a vaccine comprising at least one NIMR polypeptide and an acceptable carrier, classified in class 514, subclass 2.
- VIII. Claims 31 and 32, drawn to compositions comprising a compound that modulates NIMR activity, classified in class 439, subclass 139.1.

For Group I above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of groups I-X, and, if group I is elected, to one of inventions (A)- (C). Inventions (A)-(C) comprise the method of Group I, wherein the step of determining comprises:

- (A) measuring efflux of test or marker compound from the cell;
- (B) measuring the ability of the microbe to grow or remain viable; or
- (C) measuring ability of compound to bind NIMR.

For group II above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of groups I-X and, if group II is elected, to one of inventions (D)- (F). Inventions (D)-(F) comprise the method of Group II, wherein the step of determining comprises:

- (D) measuring the amount of RNA produced by the cell;
- (E) measuring the amount or activity of a reporter gene product produced by the cell; or
- (F) measuring that ability of an antibody to bind to the reporter gene product.

3. For each of groups I-VI above, restriction to one of the following Inventions is also required under 35 USC 121. Therefore, election is required of one of groups I-X and,

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if Group I is elected, then election is also required to one of the inventions listed in Claims 2 and 6 as filed;
if Group II is elected, then election is also required to one of the inventions listed in Claims 12 and 13 as filed;
if Group III is elected, then election is also required to one of the inventions listed in claim 26 as filed;
if Group V is elected, then election is also required to one of the inventions listed in Claims 22 and 24 as filed; or
if any of Groups IV or VI-VIII, election is also required of one of the NIMR molecules listed on pages 7-8 (Table 1).

The inventions are distinct, each from the others, for the following reasons:

4. Inventions (A)-(F) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to different methods of identifying NIM modulators. In each of the inventions, the method is carried out by measuring a different occurrence or product. As each of the methods measures something different, they are each using a different mode of operation. The different modes are not disclosed as usable together. The inventions are therefore distinct.

5. The inventions listed in the sub-election of paragraph 3 above are each unrelated to the other inventions listed in the same Group. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to modulators of different proteins. The target proteins each have different structures, and perform different functions. Therefore, modulators of these different proteins will likewise have different structures and have different effects (they will modulate different protein

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functions). Neither the proteins, nor their modulators have been disclosed as usable together. The inventions are therefore distinct.

6. Groups I, II, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to methods of identifying different NIMR modulators. The modulators of Group I are NIMR activity modulators that bind to NIMR proteins; those of group II are NIMR expression modulators; and the modulators of Groups V are NIMR activity modulators that bind to NIMR polynucleotides. Group II performs a different function from the other two groups. Groups I and V each have a different mode of operation (they function by targeting different molecules). As the modulators are not disclosed as usable together, and because they either perform different functions or have different modes of operation, the groups are distinct.

7. Groups III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different groups relate to methods that produce different effects. As each of the methods produces a different effect, and they are not disclosed as usable together, the groups are distinct.

8. Groups VIII and Groups III and IV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Group IV may be used with several materially

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different products. See paragraph 5 above (explaining how the inventions listed paragraph 3 are different). As the methods of Groups III and IV may be practiced with any of the materially distinct products of Group VIII, it is distinct from all of those inventions. Further, the compositions of Group VIII may be used in either of the methods of Groups III or IV.

9. Groups VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different groups each relate to a different type of molecule. Group VI reads on NIMR nucleic acids, Group VII on NIMR polypeptides, and Group VIII on NIMR modulators. Each of these molecule types performs a different function. None of them are disclosed as usable together. Therefore, the Groups are distinct.

Conclusion

10. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

11. A telephone call was made to Megan E. Williams on September 22, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

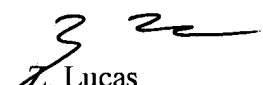
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
September 25, 2003


JAMES HOUSEL 9/30/03
SUPERVISORY PATENT EXAMINER
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